

No. 31015/2/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Ajanta Pharma Ltd. against price fixation of Azithromycin and Dexamethasone Phosphate Eye Drops 3 ml. vial vide NPPA order No. S.O. 583(E) dated 24/02/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 01.03.2016
2) NPPA notification under review S.O. No.583(E) dated 24.02.2016
3) Record Note of discussions held in the personal hearings held in the matter on 25.4.2016 & 30.5.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Ajanta Pharma Ltd. (hereinafter called the petitioner) against notification S.O. No.583(E) dated 24.02.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Dexamethasone Phosphate Eye Drops 3 ml. vial.

2. The petitioner has contended as under:

- a. They have submitted an application for price fixation of the said product in Form I to NPPA on 16th July, 2015.
- b. Based on their application, captioned order no. S.O. 583(E) was issued on 24th February, 2016.
- c. Their review application is based on following facts:
 - a. Their own product Zaha Eye drops with FDC of Azithromycin is already there in market with Retail Price of Rs. 88.57 for 3ml, whereas NPPA has approved Retail Price of Azithromycin in combination with Dexamethasone Phosphate Eye Drops Rs. 76.02, which is very low.
 - b. Their product, i.e. Azithromycin and Dexamethasone Phosphate Eye Drops 3 ml. vial, is therapeutically more beneficial and effective than other manufacturer with FDC of Moxifloxacin and Difluprednate having higher MRP, as given below:

SR	FDC	Manufacturer	Brand	MRP(Rs.)
1.	Moxifloxacin and Difluprednate	Sun Pharmaceuticals Ltd	Milflox Df	151.00

- c. Also note that a single FDC of Moxifloxacin brand prices are even more than the released Retail Price which is having dual combination.

They requested for a revised calculation based on para 4 of the DPCO, 2013.

3. The contentions of petitioner and the NPPA were heard on 25.4.2016 & 30.5.2016. During the hearings, they mentioned that NPPA fixed retail price of Azithromycin and Dexamethasone phosphate combination at Rs.76.02/3 ml which is very low whereas the single ingredient Azithromycin being marketed by them is priced at Rs.88.57 /3ml. The company representative further informed that the eye drop “Dexamethasone phosphate and Azithromycin” is a new product which came after lot of clinical trials and research and the price of this product should obviously be more than the price of Azithromycin which is a single ingredient product being marketed by them. The company representative also mentioned that M/s Alembic Ltd. is also marketing single ingredient Azithromycin at Rs.92.43/3 ml. (PTR).

4. NPPA representative requested the hearing authority to direct the company to submit the documents / information as per OM F.No.19(714)/2016/Div.II/DP/NPPA, dated 20th May, 2016, which states that ***“all the companies aggrieved by NPPA’s price fixation may make representations, if any, against the ceiling prices fixed by the NPPA, by submitting documents / information of Price to Retailer (PTR) and Moving Annual Turnover (MAT) data along with supporting documents like copies of invoices to retailer and samples of August, 2015 duly self-attested with name, designation, mobile no., signature & seal of the authorised officer of the company, within 15 days of the price notification in order to enable NPPA to take necessary action in this regard.”*** The company representative submitted the copy of the letter containing relevant documents / information with data on 31.5.2016, as required under the abovementioned OM of NPPA dated 20th May, 2016.

The NPPA representative stated that the same will be examined by NPPA and may be put up in the Authority Meeting of the NPPA.

4. **Decision of the Government:**

NPPA is directed to re-fix the retail price of “Azithromycin and Dexamethasone Phosphate Eye Drops 3 ml. vial” after taking into consideration all data, furnished by the petitioner company and available from other sources which may not have been considered earlier, on merit within a period of one month from the date of issue of this Order.

Issued on this, the 3rd day of August, 2016.

**(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India**

To

- 1. M/s. Ajanta Pharma Ltd.
Bayer House, Central Avenue,
Hiranandani Estate, Thane (West)-400607.
Maharashtra.**
- 2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001**

Copy to :

- 1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
- 2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
- 3. T.D., NIC for uploading the order on Department's Website**